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20 October, 1999

Office of Compliance (HFZ-300)
Atten: Electronic Product Reports
Center for Devices and Radiological Health
2098 Gaither Road
Rockville, MD 20850

Subject: Submittal as a Supplemental Report for Visible and IR Laser Aiming Module (LAM) and request for variance from Class IIIb requirements

Enclosed: Product report for Insight Technology's Laser Aiming (Visible and IR Models)

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## Dear Representative,

The report enclosed is being submitted as a Supplemental Report to Insight's August 27<sup>th</sup> 1999 Product Report for their Visible Only Laser Aiming Module, Accession # 9411585. The product described in this report has all the same assembly/test procedures and features as the visible only models, but also have IR illuminator and IR pointer features.

The report has been prepared to convey compliance as a Class IIIb laser product, however, a variance to the requirement of this classification is requested under the following conditions:

The sale of this product is being restricted to government, military and law enforcement agencies, including law enforcement personnel, under direct purchase order.

The user manual, supplied with each unit, includes detailed written instructions on the hazards related to exposure to the laser's beams. Also included in the manual is a replica of the product's label, further detailing the warnings.

All advertising and sales brochures, including data sheets, state the restriction of sales noted above and the proper laser radiation warnings.

The LAM's intended use to government, military, and law enforcement agencies in the routine execution of their duties requires specific variances in order not to compromise the user's safety. Specifically, a variance is being sought for the requirements of 21 CFR 1040.10(f)(3), (4), and (5), for reasons stated below:

Under 21 CFR 1040.10(f)(3) Class IIIb laser systems are required to incorporate remote interlock connector(s).

The LAM is designed not to allow for dismantling or servicing by the user. The unit's front, rear, and top housing parts are permanently bonded together. All servicing is done at Insight Technology, Inc.

Under 21 CFR 1040.10(f)(4) Class IIIb laser systems are required to incorporate a key control. The LAM requires both the mode selector switch, to be in operative mode position as well as use of the paddle switch or tethered remote switch to turn the unit on. An additional "key control" would limit the effective use of this product, and compromise the safety of the user.

Under 21 CFR 1040.10(f)(5) Class IIIb laser systems are required to incorporate an emission indicator.

Given the intended use of the LAM, such an audible or visible indicator or delayed emission of the lasers could seriously compromise the safety of the user.

The restriction of sales of the LAM and intended use of the LAM are consistent with other aiming devices of its' type. Safety and use of the LAM is almost intuitive to the users of this product.

If any further information about the report or the request for variance is needed, please do not hesitate to contact me.

Sincerely,

James A. Pellerin

Program Manager (ext. 1450)